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APPLICATION GUIDE FOR MEDICAL ELECTRICAL EQUIPMENT

PART 2 SAFETY PROVISIONS, APPLICATION, OPERATION AND MAINTENANCE

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APPLICATION GUIDE FOR MEDICAL ELECTRICAL EQUIPMENT

PART 2 SAFETY PROVISIONS, APPLICATION, OPERATION AND MAINTENANCE

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APPLICATION GUIDE FOR MEDICAL ELECTRICAL EQUIPMENT

PART 2 SAFETY PROVISIONS, APPLICATION, OPERATION AND MAINTENANCE

0. FOREWORD

0.1 This Indian Standard (Part 2) was adopted by the Indian Standards Institution on 30 July 1985, after the draft finalized by the Electromedical Equipment Sectional Committee had been approved by the Electrotechnical Division Council.

0.2 Safe use of medical electrical equipment depends on a variety of factors, namely:

a) Safety of the equipment,

b) Safety of electrical installation,

c) Safe and correct use/application,

d) Availability and readability of accompanying documents,

e) Operator's knowledge of safety characteristics of equipment, and

f) An effective maintenance scheme.

0.3 While Part 1 of this standard specifies general requirements, nature of hazards and electrical installations, this standard (Part 2) specifies the requirements for safety provisions in the equipment, tests, operation and maintenance.

0.4 These general guidelines apply in cases where electrical equipment is used in human or veterinary medicine under the jurisdiction of qualified authority by qualified personnel who have been adequately instructed concerning the proper use and possible hazards connected with such use.

(Human or veterinary medicine includes surgery, dentistry, and other specialities of the healing arts).

0.5 The object of this standard (Part 2) is restricted to the application of medical electrical equipment, possibility in combination with other electrical equipment in such a way that the safety of the patient and operator may be directly influenced and controlled.

0.6 This standard is based on IEC draft document 62A (Secretariat) 68 Draft — General guidelines for the safe application of medical electrical equipment (technical application code).

1. SCOPE

1.1 This standard (Part 2) specifies requirements for safety provisions in medical electrical equipments, tests, indication of allowable equipment and installation for treatment procedure, preventive measure before and during operation of equipment and preventive maintenance procedure, for medical electrical equipment.

2. TERMINOLOGY

2.1 Provision of **2** of Part 1 of this standard shall apply.

3. SAFETY PROVISIONS IN EQUIPMENT

3.1 Electrical Safety Provisions in Equipment

3.1.1 *Degree of Protection* — Equipment may be classified according to the degree of protection against electric shock. The degree of protection is determined by the maximum allowable leakage current. The degree of protection against electrical shock shall be indicated in the accompanying documents and symbols on the equipment. The equipment shall satisfy the safety requirements against electric shock as specified in IS : 8607 (Part 2)-1978*.

Visual and/or audible indicators shall be provided to indicate excessive leakage current, fault condition and such conditions as asking for preventive measure. Possibility of introducing devices to make the equipment inoperative in such cases may also form a part.

3.2 Mechanical Safety Provisions in Equipment

3.2.1 *Protection of Patients, Operators and Surroundings* — Medical electrical equipment should not become mechanically hazardous to the patient, operator and surroundings especially if it contains suspended or moving masses and/or automatic controls, for example, X-ray equipment, operating tables rotating machines, etc. The operator should check regularly as given in the instructions for use the functioning of the safety devices and/or alarms. In other respect, the provisions of IS : 8607 (Part 3)-1978* shall apply.

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*General and safety requirements for electrical equipment used in medical practice: Part 2 Protection against electric shock.

Any equipment or combination of equipment should not be made unstable during normal use or during transport (for example, in appropriate stacking).

3.2.2 Care should be taken so that the equipment does not fall as this could cause malfunction of the equipment. It is necessary to have equipment checked by qualified persons in order to ensure safe application in case of a fall.

3.3 Radiation Safety Provisions in Equipment — It is necessary to protect the patient, operator, equipment from the disturbing, harmful or destructive action of different kinds of radiations. The equipment shall satisfy the requirement of IS : 8607 (Part 4)-1985†.

3.4 Safety Provisions in Equipment to Protect Against Explosion

3.4.1 *The Use of Flammable Anaesthetics* — The allocation of electrical equipment in areas in which flammable anaesthetics and/or flammable agents for disinfection and/or skin cleaning are mixed with air, or with oxygen or nitrous oxide is very important.

Ignition of such a mixture may be caused by sparks or by contact with parts having a high surface temperature. Sparks may be caused where electrical circuits are opened or closed by operation of switches connectors fuses or circuit breakers and the like. In high voltage parts sparks may be caused by corona. Static discharges may also cause sparks. The probability of ignition of such anaesthetic mixtures depends on their concentration, minimum ignition energy, the presence of high surface temperatures, and the energy of sparking. The hazard caused by an ignition depends on the location and on the relative quantity of the mixture.

Details of different zone of risk, allowable equipment in such areas, requirements for electrical equipment and its marking intended for use in such areas are described in IS : 8607 (Part 5)-1983‡. Requirements for the safety provisions in the electrical installation are given in IS : 7733-1975*.

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*General and safety requirements for electrical equipment used in medical practice: Part 3 Protection against mechanical hazards.

†General and safety requirements for electrical equipment used in medical practice: Part 4 Protection against unwanted or excessive radiation.

‡General and safety requirements for electrical equipment used in medical practice: Part 5 Protection against explosive hazards.

It is recommended to use an antistatic floor and a ventilation system in the operation room with the following characteristics:

a) Air exchange in the room 20 times the total volume of the room per hour.

b) Air temperature 21 to 24°C.

c) Relative humidity 50 to 65 percent.

3.5 Safety Provisions in Equipment to Protect Against Excessive Temperature Fire and Other Hazards

3.5.1 In order to protect patient, operator and the environment unacceptable temperature rises from equipment during normal use are not allowed. The equipment shall satisfy the requirements of IS : 8607 (Part 6)†.

3.5.2 A sufficient degree of protection against hazards caused by overflow, spillage, leakage, humidity, moisture, cleaning, sterilization and disinfection is required.

Equipment containing liquids, vapours of gases shall incorporate safeguards against the risk of excessive pressure.

3.6 Safety Provisions in Equipment to Prevent Human Errors

3.6.1 Safety provisions to reduce the risk of human errors should be included in the equipment and described in the accompanying documents. [*see* IS : 8607 (Part 8)†]

3.6.2 Such provisions may concern:

a) Effective earthing as applicable,

b) Application of electrical voltage to the patient,

c) Water tightness of footswitches,

d) Prominent marking of warnings,

e) Cables,

f) Controls and switches,

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*Code of practice for electrical wiring installations in hospitals.

†General and safety requirements for electrical equipment used in medical practice:

Part 6 Protection against excessive temperature air and other hazards.

Part 8 Behaviour and reliability.

g) Medical gas systems,
h) Electrostatic charges,
j) Biological compatibility of materials,
k) Interruption of power supply,
m) Overload,
n) Fault conditions,
p) Audible and visual indicators and alarms,
q) Combinations of equipment, and
r) Environmental factors.

4. CHECKING SAFETY PROVISIONS OF EQUIPMENT

4.1 General

4.1.1 In order to check the safety provisions in equipment at least the following aspects shall be checked:

a) Resistance of protective earth conductor of Class 1 equipment;
b) Condition of supply cords and plugs;
c) Leakage currents;
d) Mechanical safety provisions by visual inspection;
e) Safety provisions to protect against the hazards of by visual inspection, as prescribed in the accompanying document;
f) Measuring temperatures of accessible surfaces;
g) Inspection of the protection against hazards caused by overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection;
h) Availability and readability of accompanying documents; and
j) Markings on equipment.

WARNING 1 : ELECTRICAL MEASUREMENTS SHALL NOT BE CARRIED OUT WHILE THE EQUIPMENT IS CONNECTED TO THE PATIENT.

WARNING 2 : MOST OF THE TESTS MENTIONED IN DIFFERENT PARTS OF IS : 8607* SHALL NOT BE CARRIED OUT IN THE HOSPITAL. THE TESTS ARE MEANT FOR MANUFACTURERS' USE.

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*General and safety requirements for electrical equipment used in medical practice.

5. ACCEPTANCE TESTS

5.1 Medical electrical equipment may have been type tested by the manufacturer or the approved testing authority on behalf of the manufacturer. Further type testing is not recommended.

5.2 Nevertheless, it is important that all medical electrical equipment should be inspected as soon as possible after its receipt by the hospital to check that the equipment is complete with the specified accessories and that it has not been damaged in transit.

5.3 It is recommended that the following inspections and tests are carried out:

a) Check that the packing is intact;

b) Check that the equipment is free from obvious external damage;

c) Check that the equipment, is of the exact type specified in the contract;

d) Check that any accessories are as specified by the purchaser;

e) Check that there is appropriate documentation;

f) Check that internal assemblies (for example, plug-in components)

g) Check the security of control knobs;

h) Check the liquid levels;

j) Check that wheels, castors, and brakes are in working order;

k) Check the marking on outside of the equipment;

m) Check that the cord grip is secure;

n) Check that the fuses are correctly rated;

p) Check the correctness of any mains-voltage setting;

q) Check that there is electrical continuity between the mains plug earth pin and accessible conductive parts of Class I Equipment which are intended to be protectively earthed;

r) Check that leakage currents are of acceptable values;

s) Check controls for smooth and positive action;

t) Check that indicator light and audible indicators are functioning;

u) Check for all 'self calibration' and 'self checks' system for correctness;

w) Check for hazards of any peculiar behaviour of the equipment when operated normally; and

x) Check that all the output levels are within the specified limits before the same is applied to the patient.

6. INDICATION OF ALLOWABLE EQUIPMENT AND INSTALLATIONS FOR TREATMENT PROCEDURES

6.1 Choice of Equipment — The following medical procedures should be performed with equipment of the type indicated:

a) Medical procedures of Category MP1 may be performed with Type B, Type BF, or Type CF equipment;

b) Medical procedures of Category MP2 may be performed with Type B, Type BF, or Type CF equipment, although Type BF and CF should be used for extra safety; and

c) Medical procedures of Category MP3 should be performed only with Type CF equipment.

If two or more procedures are performed simultaneously, the equipment type used for each should be appropriate for that procedure.

Installation should be suitable for the highest category procedure. Procedure as laid down in Part 1 of this standard shall be followed.

7. PREPARATION OF EQUIPMENT BEFORE USE

7.1 Preliminary Inspection of Equipment — Before activating equipment or connecting it to a patient:

a) Visually inspect the equipment for outward signs of damage;

b) Obtain the operating instructions and study them;

c) Check to ensure that the equipment is marked as complying with the testing authorities who inspect medical electrical equipment in the same region or country;

d) Take special notice of any warning signs fixed to the equipment;

e) Remove all fluid-filled containers from the vicinity of the equipment;

f) Check that consumable supplies are provided, check for expiry dates for such consumables, if marked; and

g) Remove any packing or restraining equipment :

In addition to the above tests, which should be performed by the operator each time before using the equipment, the engineering department or group responsible for equipment maintenance should regularly;

h) Ensure that all aspects of equipment performance are within specifications, and that all documents necessary for the safe use of each item of equipment are readily accessible;

j) Perform the safety checks described in **4**. It is especially important to do this when the equipment is first received by the hospital;

k) Advise the operator on the safe operation of equipment, the compatibility of different types of equipment, and the suitability of particular types of equipment for specific procedures; and

m) Make recommendations to the appropriate hospital staff concerning the removal from service of any equipment that is hazardous or obsolete.

7.2 Preliminary Activation of Equipment — Many faults can be discovered simply by turning on the equipment and performing checks during normal operation of the equipment. Wherever possible, the equipment should not be connected to the patient at this stage, and any indication that the equipment is unsafe should cause it to be removed from use for a technical inspection, particularly if the equipment is in operation overheats, emits smoke or delivers electric shocks. When equipment successfully passes the preliminary activation test and is safe to operate, it may be prepared for connection to the patient.

7.3 Connection to the Patient

7.3.1 All instructions relating to patient connection should be carefully followed, and particular care should be taken with equipment that makes direct internal contact via electrodes such as pacemaker leads. Patients are very susceptible to electric shock hazards with this type of equipment, and it is strongly recommended that the medical or paramedical staff ensure that equipment is absolutely safe from shock hazards and that they are not inadvertently touching other conductive surfaces while performing these procedures.

7.3.2 All alarms and the correct functioning of the equipment should be verified directly after activation without connecting to patient. Patient simulators are to be used for this purpose. A piece of patient-connected equipment may break down or enter an alarm condition after it has been running for some time. All patient-connected equipment should be regularly checked during use to ensure that it functions correctly, and that the patient is not being harmed by its use.

8. COMBINATIONS OR EQUIPMENT BY THE OPERATOR

8.1 Avoiding Ground Loops — Loops in the protective earth connections while using more than one equipment on one patient, shall be avoided.

The electrical installation should be in accordance with the installation requirements (*see* Part 1 of this standard).

Depending on the medical procedure earthing systems should be star-shaped in the patient environment. Earthing wires should have a sufficient cross-section to prevent voltage differences occurring during first fault conditions. Earthing shall satisfy the requirements of IS : 3043-1966*.

8.2 Interconnection of Multiple Equipment

8.2.1 *Enclosure Leakage Current* — If multiple equipment is mechanically interconnected or so positioned that the enclosures are in conductive connection, the enclosure leakage current of these combinations in the least favourable conditions is equal to the total of all individual enclosure leakage currents.

The first fault condition of one of the equipment should be considered as a first fault condition of the total combination by which an increase of the leakage current may occur.

The total enclosure leakage current in normal condition and first fault condition shall be less than the maximum allowable value and the combination in such cases should be treated as one system for the purpose of allowable leakage current.

To ensure a reliable protective earthing that if accidentally one equipment is disconnected, remaining equipment should be connected star-shaped to the central earth point. To avoid loops all earth conductors should be run close in parallel.

8.2.2 *Patient Leakage Current* — If the patient is connected at the same time to multiple equipment then the sum of the patient leakage currents, in the most unfavourable case, can be the sum of the patient leakage currents of all with the patient connected equipment.

The highest possible patient leakage current occurs if the total patient leakage current is increased by the leakage current of one equipment as a result of a first fault (for example, in case of a broken protective earth conductor).

By using floating patient circuits for the connection to the heart of the patient and not earthed transducers the patient fault leakage current, which are inadmissable, gets prevented from flowing through the heart of the patient.

8.3 Interconnection of Medical Electrical Equipment to Data Processing Equipment or Telephone Lines

8.3.1 The safety of the patient should not be influenced by interconnections which are conductively connected from:

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*Code of practice for earthing.

a) the patient or

b) Medical electrical equipment in the patient environment to medically used rooms.

(for example, computer application, signal process installations, electronic controls, TV connections).

8.3.2 For rooms where procedures for direct cardiac application are applicable, it is required in normal use that the voltage between the potential equalization busbar and the protective earth busbar shall not be higher than 10 mV.

In particular the patient leakage current shall not be higher than 10 μA and in single fault condition not higher than 50 μA.

Therefore a particular safety provision shall be applied in the interconnections, preferably at the input in the rooms where direct cardiac application is applicable (current limiters, safety-varriers, floating devices, coupler).

8.4 Interconnection of Medical Electrical Equipment to External Warning Devices — Special external warning systems outside medically used rooms which are connected to medical electrical equipment used in rooms where procedures for direct cardiac application are applicable, should be isolated with respect to the patient and the enclosure of medical electrical equipment.

8.5 Fire Protection While Using Oxygen

8.5.1 If the patient is connected to an oxygen supply special care should be taken while using spark producing equipment.

a) *Use of ventilator* — The ventilators shall be used in combination with monitoring and/or electrical controlling devices. Such units shall always be placed above the gas-driving parts to reduce the danger of ignition.

b) *The use of defibrillators* — Oxygen flow shall be stopped before operating defibrillators.

8.6 Combination of Medical and Non-Medical Electrical Equipment

8.6.1 Non-medical electrical equipment is commonly used in vicinity on the patient. It can be cleaning equipment, such as polisher and cleaner, entertainment equipment, such as radio and television receiver, patient comfort equipment, such as fan, heater and electric blanket, or conmetic equipment, such as shaver and hair dryer. This kind of equipment can be dangerous to the patient, and shall be located in a manner such as not to come in contact inadvertently with the patient.

It is preferable to use internally powered non-medical equipment where medical electrical equipment is in use. Mains operated non-medical electrical equipment is in use. Mains operated non-medical electrical equipment shall not be used in patient environment during the procedures of Category MP 3.

During procedures of Category MP 3 the use of mains powered non-medical electrical equipment should not be permitted in patient environment.

8.7 Use of Electric Blankets — Electric blankets are capable of providing high leakage currents and hence should not be used on any electrically susceptible patient. Unless the blankets is especially constructed, the leakage is generally sufficient to preclude monitoring because of the interference generated. Accordingly, where warning of an electrically susceptible patient is required, the use of alternative devices, for example, water blankets is preferred.

9. INTERFERENCE PROBLEMS

9.1 General — Areas in which measurements of potential generated by the body are performed, for example, EEG and ECG rooms, should be protected against interference which may cause a dangerous situation for the patient or may distort measurements.

NOTE — Adequate spacing between the equipment that may cause magnetic interference and the place for the examination of the patients is necessary, and the following values of magnetic field strength should not be exceeded:

ECG recording $3{\cdot}8 \times 10^{-7}\, T_{p\text{-}p}$ (50 Hz)
$3{\cdot}2 \times 10^{-7}\, T_{p\text{-}p}$ (60 Hz)
EEC recording $1{\cdot}9 \times 10^{-7}\, T_{p\text{-}p}$ (50 Hz)
$1{\cdot}6 \times 10^{-7}\, T_{p\text{-}p}$ (60 Hz)

9.2 Location of Equipment — Equipment likely to generate strong stray magnetic fields, for example, transformers, motors, large power cables, ballasts of fluorescent lamps, should be installed so as to minimize the interference to equipment in the areas specified in **9.1**. These shall be done as specified in IS : 7733-1975*.

The following minimum distances between patient and equipment are recommended unless it can be shown that the values of the Note to **9.1** are not exceeded:

a) Fixed wiring with considerable load (for example, lifts and X-ray generators):

50 to 200 A	3 m
200 to 400 A	6 m
more than 400 A	9 m

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*Code of practice for electrical installations in hospitals.

b) Ballasts of fluorescent lamps (may be remote from lamps);

up to 3 ballasts	3 m
more than 3 ballasts	6 m.

9.3 Transients

9.3.1 Transient voltage peaks may disturb the performance of electromedical equipment to a hazardous degree. Such transients may result, for example, from the operation of switches, sudden alteration (rise or decay) of magnetic fields, rectifier controls, intermittent faults or high frequency resonent circuits.

Protective earthing usually is not sufficient to avoid such transients, and special precautions in the design of circuits may be necessary. In the case of magnetic fields often distance is the remedy, especially between sensitive electromedical equipment and other equipment with high power consumption, for example, X-ray machines, elevators, sterilizers as well as their feeding lines.

In other cases shielding may be necessary or means in the feeding line of the sensitive equipment.

10. PREVENTIVE MAINTENANCE

10.1 Maintenance of Equipment — All medical electrical equipment has to be maintained regularly. The purpose of preventive maintenance is to minimize the necessity of fault repair and to achieve:

a) proper function,

b) safety for patient, operator and surroundings, and

c) maximum availability.

Preventive maintenance consists of servicing done by the operator and periodic maintenance by engineering staff.

A written maintenance plan covering every item of equipment, based on legal regulations, technical standards and proposals of the manufacturers in the instructions for use shall be established.

This plan shall contain the daily servicing by the operator and the periodic maintenance by the engineering staff in case the latter is not performed by the manufacturer or his agent.

The periodic maintenance should consist at least of :

a) inspection of the integrity of all covers, insulation, cables, etc, designed to prevent access to live parts;

b) exercising of all functions of the item of verify correct operation;

c) measurement of leakge currents; and

d) measurement of the resistance between the earthing point any accessible conductive parts required to be earthed.

10.2 Maintenance of the Installation

10.2.1 *Object* — In order to ensure the continuity of the medical procedures and the safety of the patient and operator and the electrical installation in medical facilities should be kept in optimal condition by means of preventive maintenance.

10.2.2 *Preventive Maintenance*

a) Preventive maintenance may be done by careful and critical visual inspection of the installation without dismantling in order to verify that the installation is in good working order;

b) Preventive maintenance may be carried out by the technical department of the medical facility for testing the installation; and

c) Maintenance may also include checking an installation by the technical department of the medical facility in order to make thorough inspection for damage, wear or deterioration and also to ensure that the installation is correctly adjusted conforming the required standard.

This test should be carried out once a year.

10.2.3 *Explosion and Fire Protection* (*A*)

i) Measurement of the resistance of antistatic floor shall be carried out as indicated in Appendix B of Part 1 of this standard. This measurement should not be performed once a year.

ii) Testing of the control system of the ventilation system should be performed every three months.

10.2.4 *Stand by Supply Systems* (GE, E_1, E_2)

10.2.4.1 Testing of the general supply system via the automatic starting system according to the instructions for use of the manufacturer of the safety supply system shall be performed by switching off the mains power supply. When simulating an interruption of the main power supply, the reliable function of the automatic staring system should be checked.

10.2.4.2 The ventilation of the motor-generator room shall be checked to endure free ventilation.

10.2.4.3 The batteries of a permanently installed stand by power supply should be in optimal condition. Therefore it is recommended to check:

a) once a month the specific gravity of the battery liquid and the liquid level and make any necessary correction,

b) once a month the ventilation of the battery room,

c) once in two years the batteries should be replaced totally.

10.2.4.4 The battaries of the special safety supply system E_1 should be in optimal condition. Therefore, it is recommended to check:

a) once a month the specific gravity of the battery liquid and the liquid level and make any necessary corrections,

b) twice a year to load the battery with the normal load for 15 minutes, and

c) once in three years the batteries should be replaced totally.